Aventis Pasteur

—URGENT VACCINE RECALL—

Voluntary Recall of Menomune®-A/C/Y/W-135 (Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined) single-dose vials, Lots UB040AA (Expiration date 7/25/03), UB040AB (Expiration date 8/14/03), UB070AA (Expiration date 9/26/03) and UB096AA (Expiration date 9/28/03)

Voluntary Withdrawal of Menomune®-A/C/Y/W-135 (Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined) in single-dose vials (see addendum for lot numbers)

October 18, 2002

Dear Health Care Provider:

Aventis Pasteur is committed to providing our customers with vaccines of the highest purity, potency and safety. Consistent with our commitment, Aventis Pasteur is notifying all customers who have received product from lots UB040AA, UB040AB, UB096AA or UB070AA of Menomune®-A/C/Y/W-135 (Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined) of a potency failure in the vaccine's stability testing that may affect its efficacy in preventing serogroup A meningococcal disease. This failure does **NOT** affect the vaccine's efficacy against serogroups C, Y, or W-135. Ten-dose vials of Menomune®-A/C/Y/W-135 are **NOT** affected by this recall.

As a precautionary measure, Aventis Pasteur is also voluntarily withdrawing all single-dose vials of Menomune®-A/C/Y/W-135 because single-dose vials may fail potency standards for serogroup A before the expiration date. The vaccine met specifications at the time of release and it is our assessment that the vaccine was potent for at least six months after release. We believe that most product from the recalled and withdrawn lots was used within six months of release.

We believe no product from lots UB040AA, UB040AB, UB096AA or UB070AA remain; however, to ensure that there are no remaining supplies, we ask that you promptly examine your inventory. If you have any remaining single-dose vials including single-dose vials in five-dose packaging, **DO NOT USE THESE DOSES.** We strongly recommend that you follow the procedures outlined in this recall letter and in the ATTACHED INSTRUCTION SHEET AND PACKING LIST.

To the best of our knowledge, serogroup A does not circulate in the U.S. (Centers for Disease Control and Prevention maintains nationwide active and passive surveillance for meningococcal disease and has identified only one serogroup A case in the last 10 years). The vast majority of Menomune®-A/C/Y/W-135 is administered to college students and others not traveling to countries where serogroup A disease is present.

A number of states have passed legislation requiring colleges and universities to provide their students with information about meningococcal disease and access to immunization. These recommendations were based on an increased risk of serogroup C disease in college freshmen who live in dormitories. U.S. college students should not be at risk for serogroup A disease unless they travel to countries that pose a high risk for contracting serogroup A *Neisseria meningitidis*.

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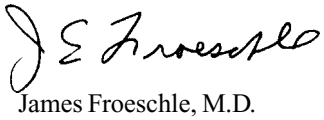
Revaccination with Menomune®-A/C/Y/W-135 for protection against serogroup A disease should be considered for the following individuals who were vaccinated since January 2, 2001:

1. Persons with laboratory or industrial exposure to serogroup A; or
2. Travelers to certain parts of the world. Serogroup A is responsible for epidemic and endemic meningococcal disease in the African "meningitis belt," which includes parts of Benin, Burkina Faso, Cameroon, Chad, Ethiopia, Gambia, Ghana, Mali, Niger, Nigeria, Senegal and Sudan.[1] In addition, serogroup A epidemics have occurred in Burundi, Rwanda, and the United Republic of Tanzania.[2] Outbreaks have also occurred in association with the annual Hajj pilgrimage in Saudi Arabia.[3] Periodically, epidemic serogroup A meningococcal disease occurs in other regions of the world. Information about geographic regions where serogroup A meningococcal disease is present can be found at www.cdc.gov/travel.

Health care providers are asked to include this recall and withdrawal notification in patient files for reference to determine if revaccination is needed for travel in the future. For your reference, we have enclosed a medical statement to provide further information. Should you have any questions, please call the Aventis Pasteur Medical Information Services Department at 1-800-752-9340.

This voluntary recall and withdrawal is being conducted with the knowledge of the U.S. Food and Drug Administration. Please accept our apologies for any inconvenience we may have caused. You are a valued Aventis Pasteur customer and we greatly appreciate your cooperation.

Very truly yours,



James Froeschle, M.D.
Director, Scientific & Medical Affairs

[1] Health Information for International Travel, Center for Disease Control and Prevention, 2001-2002
[2] Communicable Disease Surveillance and Response (CSR), *WHO*: September 4, 2002
[3] Communicable Disease Surveillance and Response (CSR), *WHO*: April 20, 2000

MKT7474

Voluntary Withdrawal of Menomune®-A/C/Y/W-135 (Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined) in single-dose vials

Addendum

NDC 49281-489-01
Single-dose lots

UA398AA
UA400AA
UA409AA
UA418AA
UB028AC
UB030AA
UB036AA
UB044AA
UB046AB
UB047AA
UB135AA
UB167AA
UB204AB
UB206AA
UB207AA
UB284AB
UB296AB

NDC 49281-489-05
Single dose lots in five-dose packaging

UA368AB	UA437AB	UB049AB	UB271AA
UA394AA	UA437AC	UB056AB	UB280AA
UA395AA	UB015AA	UB057AB	UB282AA
UA395AB	UB015AD	UB060AA	UB283AA
UA398AB	UB016AB	UB060AB	UB288AA
UA399AA	UB016AC	UB069AA	UB295AA
UA399AB	UB029AA	UB075AA	UB297AA
UA408AA	UB030AB	UB076AA	UB299AA
UA408AB	UB034AA	UB084AA	UB303AA
UA410AA	UB034AB	UB104AA	UB313AA
UA411AA	UB035AA	UB106AA	UB318AA
UA414AA	UB036AC	UB118AA	
UA414AB	UB039AA	UB148AA	
UA418AB	UB039AB	UB152AA	
UA419AA	UB043AA	UB170AA	
UA419AB	UB043AC	UB225AA	
UA420AB	UB048AB	UB261AA	

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